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Jacqueline C. Timans

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DNAX RESEARCH INC.
LEGAL DEPARTMENT
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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED OFFICE ACTION

Applicant's amendment filed on 17 April 2008 is acknowledged and entered. Following the amendment, claim 38 is canceled, and claims 52 and 54 are amended.

Currently, claims 16, 26-33, 37 and 40-57 are pending, and claims 16, 26-33, 37, 40 and 51-57 are under consideration. 16, 26-31, 33, 37, 40, 51, 52 and 55-57

Withdrawal of Objections and Rejections:

All objections and rejections of claim 38 are moot as the applicant has canceled the claim.

The new matter rejection of claims 52 and 54 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendment.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 26-31, 33, 37, 40, 51, 52 and 55-57 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an isolated polypeptide of SEQ ID NO:2 capable of binding to the receptor of SEQ ID NO:12, does not reasonably provide enablement for claims to an isolated polypeptide comprising at least 17, 20, 25, 30, 35, 50 or 75 amino acids of SEQ ID NO:2, binding to WSX-1/TCCR (claims 16, 26-31 and 40, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the previous Office Actions mailed on 2/6/07, 8/21/07 and 1/24/08.

Applicants argument filed on 17 April 2008 has been fully considered, but is not deemed persuasive for reasons below.

At pages 6-7 of the response, the applicant presented the similar argument as that in the previous response as that the test for enablement is whether experimentation alleged to be necessary is undue, not whether any experimentation is necessary; that the possible number of sequences decreases as the specified number of amino acids in a fragment increase; that it is easily within the skill of a skilled artisan to generate and identify the fragments and test for WSX-1/TCCR binding using routine methods and the teachings herein; and that the Examiner has indicated that a fragment of 17 amino acids is unlikely to possess the desired functional property, i.e., binding to WSX-1/TCCR and the Applicants request that the Examiner provide some evidence for this assertion. This argument is not persuasive because even if making and testing polypeptide fragments are routine, it is unpredictable that a fragment of 17 amino acids (out of 242 amino acids) would possess the desired functional property. Although certain regions of the polypeptide may not be essential for the functional activity, it is generally true that the retention of the functional activity of a fragment of a polypeptide becomes increasingly unpredictable while the size of the fragment decreases. Given the fact that the present polypeptide of SEQ ID NO:2 is a ligand of 242 amino acids, and a fragment of 17 amino acids is less than 1/10 (about 1/14) of the polypeptide in length, it is highly unpredictable that such a fragment would maintain the same functional property as that of the full length polypeptide. Therefore, the burden is on applicants to provide fact or reasoning to establish enablement for the claimed invention. As the instant application provides no facts or evidence to support the claimed functional fragments, such as guidance/working example of the fragment meeting the limitation of the claims, and the structural and functional relationship of the polypeptide, applicants argument is unsound, and the invention remains non-enabled.

Claims 16, 26-31, 33, 37, 40, 51, 52 and 55-57 remain further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous Office Actions mailed on 2/6/07, 8/21/07 and 1/24/08.

Applicants argument filed on 17 April 2008 has been fully considered, but is not deemed persuasive for reasons below.

At pages 7-8 of the response, the applicant argues that the claims are directed to various length polypeptide fragments of SEQ ID NO:2, which is a 242 amino acid polypeptide; that the specification discloses several specific sections, such as those on pages 8, 10 and 11, and indicates "[t]hese amino acid sequences... are important in providing sequence information for the cytokine allowing for distinguishing the protein antigen from other proteins and exemplifying numerous variants", and allow preparation of peptides to generate antibodies to recognize such segments (pages 10 and 11); that the specification also provides synthetic methods for producing polypeptides and polypeptide fragments of SEQ ID NO:2 (page 31), and shows that IL-27 binds to WSX-1/TCCR (Example XII. D.), thus, the polypeptides and polypeptide fragments that bind to WSX-1/TCCR as claimed are well-defined by SEQ ID NO:2, one of skill in the art would consider the subject matter of the claims clearly articulated. This argument is not persuasive because the supporting content in the specification pointed by applicants is less relevant as none of it is related to the claimed *functional* fragments, or to the correlation of the structural and functional relationship of the polypeptide of SEQ ID NO:2. For example, on pages 8 and 11 of the specification, it describes fragments in relationship to the structural domain boundaries of helices A, B, C, and D of the polypeptide, and there is no mention as to how the helices or the fragments correlate to the WSX-1/TCCR binding property. Further, the general teachings of preparation of peptide segments ("protein antigen") for generating antibodies thereto are not useful in making functional fragments as they are two different concepts, and an antigenic fragment does not equal to a functional fragment. Contrary to applicants argument that the polypeptide fragments that bind to WSX-1/TCCR as claimed are well-defined by SEQ ID NO:2, there is no evidence in the specification that such has been defined. Furthermore, the issue is not whether the synthetic methods for producing polypeptide fragments are known to one of skill in the art, rather, the issue is that there is no written description in the disclosure for the claimed functional fragments of the polypeptide of SEQ ID NO:2. The compound itself is required. See

Art Unit: 1647

Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

At pages 8-9 of the response, the applicant repeatedly argues that applicants have provided SEQ ID NO:2, which contains each of the sequences recited by the claims; that methods for synthesizing peptides are disclosed and well known in the art, and methods of making and using the claimed polypeptides are also provided; and that given all the information provide in the specification, one of skill in the art would consider the subject matter of the claims clearly articulated. This argument is not persuasive for the reasons above.

Conclusion:

Claims 32, 53 and 54 are allowable.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/16/08

/Lorraine Spector/Ph.D.
Primary Examiner, Art Unit 1647